

JUN 10 1998

Medical Scientific, Inc.  
125 John Hancock Blvd.  
Taunton, MA 02780

**Evansece Scar Management System**  
510(k) Premarket Notification  
April 15, 1998

13. 510(k) SUMMARY: K 981387

OVER THE COUNTER USE OF EVANESCE SCAR MANAGEMENT  
SYSTEM FOR THE TOPICAL MANAGEMENT OF HYPERTROPHIC AND  
KELOID SCARS.

13.1 CONTACT:

Paul Nardella  
Medical Scientific, Inc.  
125 John Hancock Rd.  
Taunton, MA 02780

Tel: 508-880-7313  
Fax: 508-880-7347

13.2 SPONSOR:

Medical Scientific, Inc.  
125 John Hancock Rd.  
Taunton, MA 02780

Tel: 508-880-7313  
Fax: 508-880-7347

Paul Nardella

13.3 DEVICE NAME:

A.) TRADE NAME:

EVANESCE Scar Management System

B.) COMMON NAME:

Silicone Elastomer Sheeting for the treatment and  
managment of hypertrophic and keloid scars

C.) CLASSIFICATION NAME:

Not Available

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#### 13.4 PREDICATE DEVICE:

##### SCAR HEAL

Specialty Systems, Inc.  
1312 Veracruz Lane  
Weston FL 33327

510(k) K971468

#### 13.5 DEVICE DESCRIPTION

The Evanescce Scar Management System is composed of a sheet of soft, flexible, translucent silicone elastomer.

#### 13.6 INTENDED USE:

The Evanescce Scar Management System is intended for the over the counter, topical treatment and management of hypertrophic and keloid scars. Do not use on open wounds.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 10 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Paul C. Nardella  
•Medical Scientific, Incorporated  
125 John Hancock Road  
Taunton, Massachusetts 02780

Re: K981387  
Trade Name: Evanesce Scar Management System  
Regulatory Class: Unclassified  
Product Code: MDA  
Dated: April 14, 1998  
Received: April 16, 1998

Dear Mr. Nardella:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

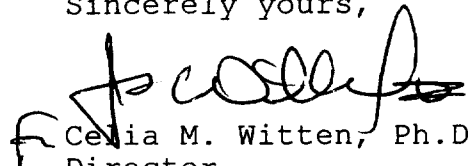
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Paul C. Nardella

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Witten', with a stylized flourish at the end.

Cecilia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number (if known):K981387

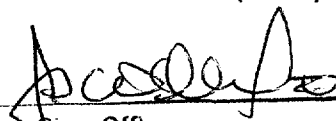
Device Name: Evanesce Scar Management System

Indications for Use:

The Evanesce Scar Management System is intended for the over the counter topical management of Hypertrophic and Keloid Scars

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K981387

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

or

Over-The-Counter Use X

(Optional Format 1-2-96)